

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION**

|   |   |                        |
|---|---|------------------------|
| MORTON GROVE<br>PHARMACEUTICALS, INC.         | ) |                        |
|   | ) |                        |
|   | ) |                        |
| Plaintiff,                                    | ) |                        |
|   | ) | No: 08-CV-1384         |
| v.  | ) |                        |
|   | ) |                        |
| THE NATIONAL PEDICULOSIS<br>ASSOCIATION, INC. | ) | Judge Bucklo           |
|   | ) | Magistrate Judge Mason |
|   | ) |                        |
| Defendants.                                   | ) |                        |
|   | ) |                        |
|   | ) |                        |

**PLAINTIFF’S MOTION TO STRIKE ALLEGATIONS AND DEFENSES  
IN DEFENDANT’S ANSWER AND COUNTERCLAIM**

**EXHIBIT INDEX**

|           |  |
|-----------|--|
| Exhibit A | June 18, 2007 Memorandum Opinion and Order, Docket Entry 86 in Case No. 06-CV-3815 |
| Exhibit B | Lists of statements from NPA’s counterclaim that should be stricken                |

# **EXHIBIT A**

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS  
EASTERN DIVISION

MORTON GROVE PHARMACEUTICALS, INC., )  
)  
Plaintiff, )  
)  
v. ) No. 06 C 3815  
)  
THE NATIONAL PEDICULOSIS )  
ASSOCIATION, INC., ECOLOGY CENTER, )  
INC., JOHN FLIEGEL, MD, WILLIAM B. )  
WEIL, MD, )  
)  
Defendants. )

MEMORANDUM OPINION AND ORDER

Defendant the National Pediculosis Association, Inc. ("NPA") has brought a motion to dismiss the complaint brought by plaintiff Morton Grove Pharmaceuticals, Inc., ("MGP") for failure to state a claim under FED. R. CIV. P. 12(b)(6). For the following reasons, the motion to dismiss is granted in part and denied in part.

I.

MGP is a pharmaceutical company that manufactures Lindane Lotion and Lindane Shampoo ("collectively Lindane"), which are FDA-approved medications for the treatment of lice and scabies. These products are named after their active ingredient - lindane.<sup>1</sup> Presently, MGP is the only United States manufacturer and distributor of Lindane. (Compl. at ¶¶ 1, 4.)

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<sup>1</sup>In order to distinguish MGP's "Lindane" products from the ingredient, the former is capitalized throughout this Memorandum Opinion and Order except when quoting the complaint.

NPA is a non-profit, tax exempt organization "dedicated to protecting children from the misuse and abuse of potentially harmful lice and scabies pesticidal treatments." (Compl. at ¶ 2.) NPA sells the LiceMeister comb, which the complaint alleges is a competing product of Lindane's.

MGP has filed claims for a violation of the Lanham Act, 15 U.S.C. ¶ 1125(a) (Count I); defamation (Count II); trade disparagement (Count III); and violations of the Illinois Uniform Deceptive Trade Practices Act ("UPTPA"), 815 ILCS 510/2 *et. seq.* (Count IV) against NPA based on alleged false statements made by NPA.

## II.

In assessing defendant's motion to dismiss under FED. R. CIV. P. 12(b)(6), I must accept all well-pleaded facts in the complaint as true. *Moranski v. Gen. Motors Corp.*, 433 F.3d 537, 539 (7th Cir. 2005). Documents attached to the complaint are considered part of the complaint. *Id.* (citing FED. R. CIV. P. 10(c)). I must view the allegations in the light most favorable to plaintiff. *Id.* However, "[f]actual allegations must be enough to raise a right to relief above the speculative level." *Bell Atl. Corp. v. Twombly*, 550 U.S. --, 127 S. Ct. 1955, 1965 (May 21, 2007).

A. Count I: Lanham Act

Defendant moves to dismiss the Lanham Act ("the Act") claim on the grounds that MGP lacks standing to sue under the Act and that NPA's statements are not advertisements. "To establish a claim under the false or deceptive advertising prong of § 43(a) of the [Lanham] Act, a plaintiff must prove: (1) a false statement of fact by the defendant in a commercial advertisement about its own or another's product; (2) the statement actually deceived or has the tendency to deceive a substantial segment of its audience; (3) the deception is material, in that it is likely to influence the purchasing decision; (4) the defendant caused its false statement to enter interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the false statement, either by direct diversion of sales from itself to defendant or by a loss of goodwill associated with its products." *Hot Wax, Inc. v. Turtle Wax*, 191 F.3d 813, 819 (7th Cir. 1999) (citation omitted). In order to have standing to bring a false advertisement claim, a plaintiff must have "a discernible competitive injury." *L.S. Heath & Son, Inc. v. AT&T Info. Sys., Inc.*, 9 F.3d 561, 575 (7th Cir. 1993); *Gail Green Licensing & Design Ltd. v. Accord, Inc.*, No. 05 C 5303, 2006 WL 2873202, at \*5 (N.D. Ill. Oct. 5, 2006) (St. Eve, J.). A party must have "a reasonable interest to be protected against conduct violating the Act." *Johnny Blastoff, Inc. v. Los Angeles Rams Football Co.*, 188 F.3d 427, 438 (7th Cir. 1999)

(quoting *Dovenmuehle v. Gilledorn Mortgage Midwest Corp.*, 871 F.2d 697, 700 (7th Cir. 1989)).

In this case, the complaint alleges that the parties' products, Lindane and LiceMeister, are in competition. (See Compl. at ¶¶ 2, 23, 30, 32.) Although NPA may be a non-profit organization, the complaint does allege that LiceMeister accounted for 97% of NPA's revenues in 2003 and that it has profited from the sales of such a product. (Compl. at ¶¶ 2, 10.) Meanwhile, "[a]s a result of [d]efendant's[sic] statements, Lindane sales have decreased approximately 23%, with a total loss of more than \$9.3 million between January and November 2006." (Compl. at ¶ 37.) Taken as true, these allegations sufficiently set forth MGP's alleged discernable competitive injury. Accordingly, on the face of the complaint, MGP has standing under the Act.

Similarly, the complaint alleges that "NPA has launched an attack campaign against Lindane in the hopes that it can increase sales of the LiceMeister[] comb" and that this is a "for-profit" campaign. (Compl. at ¶ 23.) Some of the identified statements forming the basis of MGP's claims specifically promote LiceMeister as a product. (See Compl. at ¶ 32; Exh. A.) Defendant takes issue with whether this is "mere puffery" as opposed to advertisement; taken in the best light to plaintiff, however, the complaint sufficiently sets forth that some of NPA's statements are

commercial advertisement. Accordingly, the motion to dismiss count I is denied.

#### B. Count II: Defamation

Defendant next argues that plaintiff has failed to state a claim for defamation. Under Illinois law, a statement is considered defamatory if it "tends to cause such harm to the reputation of another that it lowers that person in the eyes of the community or deters third persons from associating with him." *Kolegal v. Heftel Broad. Corp.*, 154 Ill.2d 1, 10, 607 N.E.2d 201, 206 (Ill. 1992) (citation omitted). To establish a claim of defamation under Illinois law a plaintiff must show (1) the defendant made a false statement concerning the plaintiff; (2) there was an unprivileged publication of the defamatory statement to a third party by defendant; and (3) the plaintiff was damaged. *Dubinski v. United Airlines Master Executive Council*, 303 Ill. App. 3d 317, 323, 708 N.E.2d 441, 446-47 (Ill. App. Ct. 1999) (citation omitted). An Illinois defamation action can either state a claim for defamation *per se*, which involves statements so harmful to one's reputation that damages are presumed; or for defamation *per quod*, which involves statements requiring extrinsic facts to show their defamatory meaning. *Bryson v. News Am. Publ'ns, Inc.*, 174 Ill.2d 77, 87, 672 N.E.2d 1207, 1214 (Ill. 1996).

1. Defamation *per se*.

For a statement to be defamatory *per se* in Illinois, it must first qualify under one of five categories:

(1) statements imputing the commission of a crime; (2) statements imputing infection with a loathsome communicable disease; (3) statements imputing an inability to perform or want of integrity in performing employment duties; (4) statements imputing a lack of ability or that otherwise prejudice a party in his or her profession or business; and (5) statements imputing adultery or fornication.

*Tuite v. Corbitt*, 224 Ill.2d 490, --, 866 N.E.2d 114, 121 (Ill. Dec. 21, 2006) (citations omitted). Second, the statement cannot be reasonably capable of an innocent construction, otherwise it is not actionable *per se*. *Id.* "Whether a statement is reasonably capable of an innocent construction is a question of law for the court to decide." *Republic Tobacco Co. v. N. Atl. Trading Co.*, 381 F.3d 717, 727 (7th Cir. 2004) (citation omitted).

The alleged defamatory statements here are reasonably capable of an innocent construction. First, the statements at issue define lindane not as MGP's product, but as a chemical ingredient. (See Compl. at ¶ 23; Exh. A.) The statements in Exhibit A to the complaint provide:

Lice and Scabies Lindane Formulas

. . .  
Lindane is commonly used as a pediculicide in the USA. But the US [NPA] has maintained since 1983 that the toxicity of lindane outweighs any benefits it may have as a pediculicide. In many cases it is sold or prescribed without adequate warnings or guidance on use. . . . The lindane content in a solution of pediculicide, if consumed accidentally or deliberately, is significant.



The alternatives are the equally toxic malathion, or the relatively less toxic pyrethroid compounds.

. . .  
Kwell: One shampoo product that is only available by prescription is Kwell®. . . . Head lice resistance to lindane, the active ingredient in Kwell, has been reported in many parts of the world, including the U.S.

. . .  
Lindane is a prescription-only agent and was approved by the FDA in 1947.

. . .  
Chemicals found in lindane formulated pediculicides and scabicides  
Additional chemicals found in lindane formulated pediculicides and scabicides

. . .  
Illinois Banned Lindane

. . .  
[Illinois draft legislation] Amends the Illinois Food, Drug, and Cosmetic Act. Provides that no person shall sell, deliver, offer for sale, hold for sale, give away, use, or prescribe any product used for the treatment of lice or scabies in human beings that contains the pesticide chemical lindane.

New York Follows California to Ban Prescription Pesticide Lindane for Lice and Scabies

NY State proposes legislation banning the sale, use, and prescription of lindane. Assemblyman [] introduces bill that would prohibit any lice or scabies treatment product from containing the pesticide Lindane.

NY[] February 9, 2004 - Bill A008628 filed in the state of New York proposes to amend the public health law to ban the sale, use, and prescription of any product containing the substance commonly known as lindane, used for the treatment of lice or scabies in humans, from containing the pesticide.

The provision states, "Lindane is the working ingredient in over 2 million prescriptions for shampoos and creams meant to control head lice and scabies and that these prescriptions are issued to children, [etc.]" . . .

Also included is reference to lindane as a man made pesticide that has been categorized by the U.S. [EPA] as a persistent, bioaccumulative and toxic pollutant, meaning that it lingers for a long period in the environment, moves up the food chain and is highly toxic to human and wildlife. . . .

. . .  
What is Lindane Anyway?

For starters it is consistently ranked among the top chemicals of concern by the Agency for Toxic Substances and Disease Registry. By any other name, lindane is the 99% pure gamma isomer of hexachlorocyclohexane. It was introduced as a pediculicide and scabicide in 1952 as Kwell by Reed and Carnrick. The Pharmaceutical Manufacturing Encyclopedia describes the manufacturing process of lindane as one in which chlorine gas is gradually passed into 660 part of benzene (a known carcinogen) until 890 parts of the gas has been absorbed.

. . .  
The United States is one of very few industrialized countries still using lindane in agriculture and for lice control.

. . .  
Lindane is a persistent, bioaccumulative, and toxic organochlorine insecticide.

. . .  
Lindane is highly persistent and travels long distances via atmospheric and oceanic currents. In fact, lindane, with its isomers, is the most abundant pesticide in Arctic air and water.

. . .  
Lindane is a colorless solid with a musty odor. It is an organochlorine insecticide.

(Id.) (emphasis omitted). Such references to lindane as a chemical ingredient are found throughout Exhibit A to the complaint.

Moreover, none of the alleged defamatory statements refer to MGP at all, much less as the manufacturer of a lindane-based product. The only name-brand lindane-based product identified by name is Kwell, which is not MGP's product. Accordingly, on the face of the complaint it is clear that the statements can be reasonably read as referring to the chemical lindane and not to MGP's product.

Plaintiff does not dispute that the statements identified in the complaint do not refer to MGP. Instead, plaintiff argues that defendant's statements, in context, "clearly intended and unmistakably conveyed a defamatory meaning." *Solaia Tech., LLC v. Specialty Pub. Co.*, 221 Ill. 2d 558, 580, 852 N.E.2d 825, 839 (Ill. 2006). This argument is not supported by the language in the complaint. As described, the context of the statements serves only to reaffirm the existence of an innocent construction. Plaintiff does not point to any "context" which suggests the contrary. Moreover, because the statements are silent with respect to MGP, plaintiff necessarily relies on an extrinsic fact, *i.e.* that it has been the only United States distributor of the product Lindane for the last four years, in order to argue against an innocent construction. This is not permitted in order to state a claim for defamation *per se*. See *Bryson*, 174 Ill.2d at 87, 672 N.E.2d at 1214; *Barry Harlem Corp. v. Kraff*, 273 Ill. App. 3d 388, 390, 652 N.E.2d 1077, 1080 (Ill. App. Ct. 1995) ("Because plaintiff relies on facts outside the commentary to show that it refers to plaintiff, the commentary is not defamatory *per se*.")

Accordingly, the statements identified in the complaint are reasonably capable of an innocent construction and are not actionable *per se*.

2. Defamation *per quod*.

A cause of action for defamation *per quod* may be brought under two circumstances. First, a *per quod* claim is appropriate where the defamatory character of the statement is not apparent on its face, and resorting to extrinsic circumstances is necessary to demonstrate its injurious meaning. "To pursue a *per quod* action in such circumstances, a plaintiff must plead and prove extrinsic facts to explain the defamatory meaning of the statement." *Bryson*, 174 Ill.2d at 103, 672 N.E.2d at 1221 (citation omitted). A plaintiff must also plead special damages in order to state a claim under Illinois law, see *id.*, and comply with the heightened pleading standard of FED. R. CIV. P. 9(g), which requires special damages be specifically stated. *Muzikowski v. Paramount Pictures Corp.*, 322 F.3d 918, 927 (7th Cir. 2003) (citations omitted). "[A]n allegation of special damages is sufficient when it notifies the defendant of the nature of the claimed damages even though it does not delineate them with as great precision as might be possible or desirable." *Cont'l Nut Co. v. Robert L. Berner Co.*, 345 F.2d 395, 397 (7th Cir. 1965) (quotation omitted).

Plaintiff first moves to dismiss defendant's *per quod* claim on the ground that it did not plead special damages. The complaint does allege, however, that "[a]s a result of [d]efendants' statements, Lindane sales have decreased approximately 23%, with a total loss of more than \$9.3 million between January and November

2006.” (Compl. at ¶ 37.) This satisfies the pleading requirements under Rule 9(g) and Illinois defamation law. See *Marseilles Hydro Power, LLC v. Marseilles Land & Water Co.*, No. 00 CV 1164, 2003 WL 259142, at \*4-7 (N.D. Ill. Feb. 4, 2003) (Leinenweber, J.) (collecting Illinois and federal cases). While defendant is correct that this allegation includes the statements made by other defendants that have been dismissed from this case, for purposes of Rule 9(g) this is sufficient. See *Action Repair, Inc. v. Am. Broad. Cos.*, 776 F.2d 143, 150 (7th Cir. 1985) (“an estimation of final total dollar amounts lost is unnecessary”); *Continental Nut*, 345 F.2d at 397 (figures of gross sales before and after alleged defamatory public were sufficient under Rule 9(g)).

Defendant also moves to dismiss on the ground that MGP’s extrinsic facts are insufficient. The complaint plainly provides that MGP is the only United States “manufacturer and distributor of Lindane [Lotion and Shampoo].” (Compl. at ¶¶ 1, 4.) Although NPA disputes this allegation, I must take it as true; therefore this argument is unavailing because a reader may conclude the statements are about MGP’s product. NPA also argues that the statement’s reference to Kwell, another lindane-based lice treatment identified by name on NPA’s website, defeats the adequacy of MGP’s allegations. Regardless of whether the NPA website specifically identifies another lindane-based product, in light of the complaint’s allegation that MGP is presently the only manufacturer

and distributor of Lindane Lotion and Shampoo, the complaint manages to state a claim for defamation *per quod* based on extrinsic facts.

Next, defendant moves to dismiss on the ground that the statements at issue are protected under Illinois law and the First Amendment. "Under Illinois law, [] a statement is not actionable if it is an opinion relating to an individual's acts rather than the individual, the listener can perceive a factual basis for the statements and draw his or her own conclusions, and the statement relates to a matter of public concern." *McDonagh v. Bergan*, No. 03 C 1465, 2003 WL 21798735, at \*2 (N.D. Ill. July 25, 2003) (Moran, J.) (citation omitted). However, factually misleading statements are not protected. *Id.* at \*3; *Solaia*, 221 Ill. 2d at 581, 852 N.E.2d at 840 ("If a statement is factual, and it is false, it is actionable."). Here, the complaint alleges that the statements are factually misleading; therefore on the face of the complaint, plaintiff's claims are not barred under Illinois law or by the First Amendment.

Finally, defendant argues (1) that its statements are protected by a qualified privilege, and (2) plaintiffs have failed to plead actual malice. Illinois law protects "honest communications of misinformation in certain favored circumstances in order to facilitate the availability of correct information." *Kuwik v. Starmark Star Mktg. & Admin., Inc.*, 156 Ill.2d 16, 24, 619

N.E.2d 129, 133 (1993) (citation omitted). A qualified privilege operates as an affirmative defense. See *Babb v. Minder*, 806 F.2d 749, 753 (7th Cir. 1986); *Goldstein v. Kinney Shoe Corp.*, 931 F.Supp. 595, 598 (N.D. Ill. 1996). "A court must determine as a matter of law and general policy whether the occasion created a recognized duty or interest that makes the communication privileged." *Haywood v. Lucent Techs., Inc.*, 323 F.3d 524, 533 (7th Cir. 2003) (quotation omitted). A complaint need not anticipate or plead around affirmative defenses. See *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 901 (7th Cir. 2004); see also *Chisholm v. Foothill Capital Corp.*, 940 F. Supp. 1273, 1285 (N.D. Ill. 1996).

"Once the court decides that a qualified privilege exists, the plaintiff has the burden of showing that the defendant abused and lost the privilege." *Babb*, 806 F.2d at 753. An abuse of the privilege occurs when the defendant acts with "a direct intention to injure another, or a reckless disregard of the defamed party's rights and of the consequences that may result to him." *Kuwik*, 156 Ill. 2d at 30, 619 N.E.2d at 135 (quotation and alterations omitted). This is a factual question. *Id.* Similarly, a statement is made with actual malice when it is made with knowledge that it is false or with reckless disregard to whether it is false. *New York Times Co. v. Sullivan*, 376 U.S. 254, 279-80 (1964).

In this case, even assuming the allegations in the complaint unequivocally established that the statements were privileged, the complaint alleges the requisite intent requirement to plead an abuse of the privilege and actual malice. The complaint pleads that “[d]espite this well-documented scientific, medical and regulatory history, [d]efendants have launched an attack campaign on Lindane. Defendants swap agricultural and pharmaceutical research, selectively quoting and/or misstating findings from studies relating to the agricultural use of lindane, and widely disseminate false, misleading, and defamatory statements about the safety profile and effectiveness of Lindane.” (Compl. at ¶ 8.) The complaint also alleges that when defendants “published and communicated these statements and refused to retract them, they did so negligently or intentionally.” (Compl. at ¶ 55.) In light of these allegations, defendant’s arguments fail.

Accordingly, to the extent count II states a claim for defamation *per quod*, the motion to dismiss is denied.

C. Counts III and IV: Trade Disparagement and Deceptive Trade Practices.

Defendant moves to dismiss count II for trade disparagement and count III, which is brought under the Illinois Uniform Deceptive Trade Practices Act (“UDTPA”), 815 ILCS 510/1 *et. seq.*, on the same grounds. Both claims are subject to the same analysis: in order to state a claim for trade disparagement and under the UDTPA a plaintiff must allege that defendant published untrue or



misleading statements that disparaged the plaintiff's goods or services. See *Am. Wheel & Eng'g Co., Inc. v. Dana Molded Prods., Inc.*, 132 Ill. App. 3d 205, 211, 476 N.E.2d 1291, 1295-96 (Ill. App. Ct. 1985) (UDTPA "substantially embodies the common law tort of commercial disparagement"); *McDonagh*, 2003 WL 21798735, at \*4. As discussed in addressing plaintiff's defamation *per quod* claim, the complaint here plainly alleges that defendant published untrue and misleading statements that disparage MGP's product. Defendant argues that the statements at issue are not "of and concerning" MGP. The complaint alleges the contrary when it provides that MGP has been the sole manufacturer and distributor of lindane-based products in the United States in the past four years. Taken as true and in the best light to plaintiff, these allegations state a claim for trade disparagement and under the UDTPA.

III.

For the foregoing reasons, defendant's motion is granted in part and denied in part. To the extent that count II states a claim for defamation *per se*, it is dismissed.

ENTER ORDER:



**Elaine E. Bucklo**

United States District Judge

Dated: June 18, 2007

# **EXHIBIT B**

## NPA ALLEGATIONS THAT SHOULD BE STRICKEN

**FDA warning letter references:** ¶¶29-34, 45, 60, 77, 88-89, 99-102, and 126, and Exhibit A completely

[Heading above ¶29: ] *The FDA Warning Letter*

29. Morton Grove's aggressive promotional campaign recently prompted action by the FDA.
30. On December 13, 2007, the FDA sent Morton Grove a Warning Letter ("the Warning Letter," attached hereto as Exhibit A) informing Morton Grove that some of its advertising and promotional material contained false or misleading statements about Lindane Shampoo.
31. In the Warning Letter, the FDA described portions of previous promotional websites for Lindane Shampoo and Morton Grove's promotional newsletters as "misleading in that they omit and/or minimize the most serious and important risk information associated with the use of Lindane Shampoo, particularly in pediatric patients; include a misleading dosing claim; and overstate the efficacy of Lindane Shampoo." Further, the FDA chastised Morton Grove because the identified advertising "materials convey[ed] little sense of [the] limitation [of lindane pesticidal treatments as second-line options] and little about the magnitude and nature of the risks associated with the drug."
32. The FDA concluded in the Warning Letter that Morton Grove's advertising materials "appear[ed] to represent an attempt to downplay the significant risks associated with Lindane Shampoo use and encourage wider use, with less care, than is appropriate under approved labeling."
33. Accordingly, the FDA told Morton Grove:  
We are very concerned about the potential for significant negative health consequences in children who use Lindane Shampoo because you are promoting Lindane Shampoo as being safer and more effective for pediatric patients than has been demonstrated by substantial evidence or substantial clinical experience . . . .
34. In addition to the print marketing materials described in the FDA Warning Letter, Morton Grove has made other misleading claims while advertising Lindane Lotion and Lindane Shampoo. Not only did Morton Grove disseminate additional misleading materials prior to receiving the FDA Warning Letter, but it also continued to do so after receiving that letter, which pointed out the misleading nature of its promotional claims.
45. On information and belief, Morton Grove did not take steps to correct the misleading impressions created by these letters, even after it received the FDA Warning Letter emphasizing the misleading nature of its other materials promoting its lindane products.
60. Even after receiving the FDA Warning Letter, Morton Grove has continued to promote its lindane products by using misleading statements about their safety and efficacy.

77. As the FDA pointed out in its Warning Letter, promotional material for Morton Grove's products is misleading if it "omits critical information reflected in the Public Health Advisory and in the PI for Lindane Shampoo regarding the risks of the drug associated with normal use (which includes seizures and death)." Such materials create "the misleading suggestion . . . that serious adverse reactions will not occur when Lindane Shampoo is used as directed."

88. As the FDA pointed out in its Warning Letter, a promotional piece that "fail[s] to include **any** risk information regarding treatment with Lindane Shampoo" is misleading.

89. Specifically, Morton Grove's promotional materials are misleading if they "omit and/or minimize the most serious and important risk information associated with the use of Lindane Shampoo, particularly in pediatric patients" and "convey . . . little about the magnitude and nature of the risks associated with the drug."

99. As the FDA pointed out in its Warning Letter, Morton Grove's promotional materials are misleading if "they make prominent claims of effectiveness for Lindane Shampoo for the treatment of head lice in children but omit and/or minimize important risk information from the body of the pieces, including crucial facts about potentially fatal risks associated with the use of Lindane Shampoo in this vulnerable population," because "[t]his omission of risk information is completely at odds with the current labeling for Lindane Shampoo, which describe a drug associated with potentially fatal risks."

100. The FDA further explained that Morton Grove promotional materials that "targeted pediatric patients who are at particular risk with respect to [lindane pesticidal treatments]" were "misleading in that they omit and/or minimize the most serious and important risk information associated with the use of Lindane Shampoo, particularly in pediatric patients."

101. The FDA further identified as misleading a web page that carried a "principal message[] . . . that Lindane Shampoo offers safe and effective treatment for head lice in all children, a message plainly at odds with labeling" because "Lindane Shampoo should be used with caution in children because its use has been associated with seizures and death, and because of this risk it is a second line treatment."

102. The FDA further identified as misleading promotional material that stated only that "some products may not be suitable" for use by patients who are pregnant or breastfeeding because it "fail[ed] to convey that a patient should not use Lindane Shampoo while breastfeeding as it is present in human breast milk and may cause toxicity if ingested from breast milk."

126. Morton Grove made the statements identified in paragraphs 48-49, 51, 63, 68-70, and 73-74 with the full intention of hiding the ball and misleading the public as to the dangers of using Lindane Lotion and Lindane Shampoo, and continued to make misleading promotional and marketing claims even after the FDA Warning Letter pointed out the misleading nature of its claims. Thus, Morton Grove made these statements willfully and maliciously.

EXHIBIT A to NPA's Counterclaim

**Black box warning references:** ¶¶ 20-24, 75, 81, 87, and 94 completely

20. In conjunction with this Public Health Advisory, the FDA mandated new labeling and packaging requirements for Lindane Lotion and Lindane Shampoo, including the addition of a “black box” public health warning.

21. A “black box” warning or “boxed warning,” such as that required for Lindane Shampoo and Lindane Lotion, represents a stringent labeling requirement and reflects serious concerns on the part of the FDA as to the dangers and risks presented by use of the drug.

22. According to the black box, Lindane Lotion or Lindane Shampoo “should only be used in patients who cannot tolerate or have failed first-line treatment with safer medications.”

23. The black box emphasizes that the adverse effects associated with lindane pesticidal treatments have occurred even when they are used as directed: “Seizures and deaths have been reported following Lindane Shampoo [or Lindane Lotion] use with repeat or prolonged application, but also in rare cases following a single application according to directions.”

24. The black box also explains that lindane pesticidal treatments should be used “with caution in infants, children, the elderly, and individuals with other skin conditions, and those who weigh < 110 lbs (50 kg) as they may be at risk of serious neurotoxicity.”

75. Nowhere in the letters identified in paragraphs 67 and 72 do Dr. Shwayder or Dr. Hebert mention that the FDA’s “black box” warning requires lindane pesticidal treatments to be used “with caution” in anyone weighing less 110 pounds - in other words, most children.

81. The FDA’s mandated “black box” public health warnings for Lindane Shampoo and Lindane Lotion warns that “[s]eizures and deaths have been reported following Lindane Shampoo [or Lindane Lotion] use with repeat or prolonged application, but also in rare cases following a single application according to directions.”

87. The FDA has recognized that those considering prescribing or using lindane pesticidal treatments should be aware of and consider the risks and potential serious side effects. One purpose of the FDA’s mandated “black box” public health warning for Lindane Shampoo and Lindane Lotion is “to better inform both healthcare professionals and patients regarding the potential risks associated with the use and misuse of Lindane” because “[g]iven the possible risks associated with the use of Lindane, healthcare providers should consider this new safety information when deciding whether to prescribe Lindane Lotion or Lindane Shampoo for patients who may be at risk for serious adverse drug events.”

94. The FDA’s mandated “black box” public health warning for Lindane Shampoo and Lindane Lotion warns that the pesticidal treatments should be used “with caution in infants, children, the elderly, and individuals with other skin conditions, and those who weigh < 110 lbs (50 kg) as they may be at risk of serious neurotoxicity.”

**Black box warning references:** ¶¶ 3, 26, 28, and 97 in part annotated by strike-through

3. As part of this campaign, Morton Grove has advertised and promoted its lindane pesticidal treatments in a manner that disregards, downplays, and discounts their serious risks and use restrictions, ~~including those contained in the FDA's mandated "black box" public health warning for Lindane Shampoo and Lindane Lotion.~~

26. In response to the increasing scrutiny of the chemical lindane and its pharmaceutical uses, Morton Grove launched an aggressive advertising and promotional campaign designed to minimize the dangers and risks of using Lindane Shampoo and Lindane Lotion, ~~including those identified in the FDA's "black box" warning.~~

28. In particular, as part of its strategy to ensure continued use of Lindane Shampoo and Lindane Lotion, Morton Grove has targeted pediatricians and other health care professionals. Morton Grove seeks to convince them to write prescriptions for, or recommend use of, these products despite the increasing regulatory scrutiny of pharmaceutical lindane, and despite the risks described ~~in the FDA's black box warning and elsewhere.~~

97. The FDA's 2003 Talk Paper, issued in conjunction with its Public Health Advisory ~~and mandated "black box" warning,~~ explains that the FDA's warnings about the use of lindane pesticidal treatments in pediatric patients were "based on reports to the FDA's voluntary reporting system which described approximately one half of reported adverse events occurred in pediatric patients."